REMARKS

Reconsideration in view of the foregoing amendments and following remarks is respectfully requested.

1. Regarding Election/Restrictions. Claims 1-8 and 10 stand withdrawn as being drawn to non-elected species as required.

2. According to Applicants' records, claim 24 is also pending. Claim 24 is missing from the Office Action Summary and is also not cited in the text of the Office action.

3. Regarding Examiner's rejections based on George USP 5,014,494.

Applicants' invention is distinct in at least one key aspect from the cited prior art. Applicants have invented novel apparatus and methods which have as one key object the detection of "contamination" of the sterile, packaged device with oxygen. "Contamination" with oxygen is not a problem for most sterile medical devices, but Applicants have a special requirement to ensure portions of their device are not filled with oxygen. This unusual requirement led Applicants to the present invention which meets this special requirement in a novel way. In addition to remaining sterile in storage, Applicants' device must remain essentially free of oxygen in order for Applicants' device to be safely used in a medical procedure. The present invention is directed to verifying that oxygen has not entered the package in the weeks and months or even years after sterilization, during which time Applicants' device is shipped to a customer, and may be stored for an extended period by the customer before it is needed for a particular medical procedure. The present invention provides an obvious visual indication that a customer can easily see whether or not the device has become contaminated with oxygen during storage or handling. Thus, Applicants' device is packaged in a manner which excludes oxygen, and the interior of the package is free of oxygen during

handling and storage, even after the packaged device has been sterilized. Applicants further disclose particular structure and method so that the customer, when he handles and examines the device immediately prior to use, can easily verify that there is no oxygen contaminating the device. Applicants still further disclose a structure and method whereby the sterilization process activates or sensitizes a visual indicator, so that after sterilization, during handling and storage of the device, freedom from oxygen contamination can be more easily verified by the customer.

George, on the other hand, addresses a different problem and suggests a different structure and different method to address that problem. George describes a method of avoiding accelerated discoloration and embrittlement which can otherwise occur during sterilization, when using gamma sterilization to sterilize devices made from certain materials. George is trying to prevent visual discoloration during sterilization, as distinct from the present invention in which Applicants are trying to detect the presence of any oxygen after sterilization, during subsequent handling and storage, by providing visual changes.

Thus, George provides a method for sterilizing devices which are packaged in gas-permeable packaging in **FIG. 2** (note error in the first box incorrectly states "impermeable," whereas in column 2, lines 55-58, it correctly states "permeable"). A well known example of such packaging is Tyvek®. Such gas permeable packaging is completely unacceptable for Applicants' device since oxygen would easily pass into the package and contaminate the device during storage. The claims in George refer to the gas-permeable packaging configuration. The method of George is directed to prevention of yellowing and embrittlement which could occur during the sterilization process, such as with silicone or PVC articles. **FIG. 1** of

George outlines use of gas-impermeable packaging, but again is directed to prevention of yellowing and embrittlement which could occur during the sterilization process, such as with silicone or PVC articles. In either approach, George lacks a structure which provides visual indication of the presence of oxygen in the package after sterilization, such as during handling and storage of the device. The present invention, as claimed in claim 9, has a structural element missing from George, namely, a visual indicator--that is, material which undergoes a visual change when it is exposed to oxygen, and which is separate from the medical device which is sensitive to oxygen. In the present invention, the medical device itself need not exhibit any yellowing of visual change at all under exposure to oxygen. Alternatively, the medical device could exhibit some discoloration, but in either case the separate oxygen-sensitive material which acts as a visual indicator provides obvious indication of any oxygen contamination, even if any discoloration of the medical device is not obvious.

Therefore, the structure and method disclosed by George are different from the structure and method of the present invention, and they are directed to solving entirely different problems--George provides a method of preventing discoloration and embrittlement, whereas the present invention provides a method of detecting oxygen contamination.

Examiner's suggestion that George anticipates including more than one medical device in his package and that such configuration would be equivalent to that of the present invention is incorrect. The whole point of the George method is to prevent yellowing and embrittlement of one or more than one article. Applicants, in contrast, are trying to provide a visual change in a separate indicator material because there might be no reliable visual indication on the medical device itself that the device is contaminated with oxygen. Said

another way, George prevents visual change of one or more medical device, whereas the present invention provides visual change on an indicator to detect oxygen contamination of a medical device. Applicants believe a careful reading of the present claims will reveal the structural difference from George.

Examiner states that George discloses several polymer plastics which are known to yellow "post gamma radiation." Applicants believe this is incorrect. Rather, Applicants suggest that the disclosed polymer plastics yellow during gamma radiation. George does not suggest that these polymer plastics would yellow later, upon subsequent exposure to oxygen. This is an important distinction, because if one were to utilize the teaching of George and prevent yellowing, there would be no way of detecting oxygen contamination which occurred during handling or storage of the device. And such detection of oxygen contamination is exactly what Applicants' invention is directed to. Examiner at several points suggests that "during gamma sterilization" is somehow equivalent to "post gamma sterilization," but it is not. George also does not anticipate "activating" a material to make it sensitive to subsequent oxygen exposure. According to George, the polymer plastics are sensitive to oxygen exposure only during the time period when they are being irradiated by gamma radiation; that is, why George at column 2, starting at line 55, cites a gas-permeable package, and states at column 3, lines 1-3, that in this case oxygen would enter through the gas-permeable package. George then suggests that for articles sensitive to oxygen during storage, a (gas-impermeable) foil package may be required (according to the process of **FIG. 1**). George offers no method of detection of oxygen contamination in such cases, however. In contrast, Applicants' invention provides a visual indicator which indicates oxygen exposure at any time after sterilization.

If the George device were to be contaminated by oxygen three months after sterilization, for example, by improper opening of a shipping box piercing a portion of the sterile package and allowing oxygen to enter, the George device would offer no visual indication of such oxygen exposure. In contrast, the present invention provides a visual indication of such oxygen exposure, even if there were no oxygen exposure during the sterilization process. Thus, George neither anticipates nor renders obvious the present invention.

Examiner refers to Applicants' "admission" of "within minutes" referring to the rapidity with which certain materials might yellow or embrittle during gamma exposure. After sterilization, when the article is no longer being exposed to gamma radiation, the articles and materials of George will not yellow or embrittle within minutes. It is only during the few hours that an article is actually exposed to gamma radiation during the sterilization process that Applicants were referring to a yellowing or embrittlement within minutes. The present claims 19 and 20 refer to time periods of within 8 hours or within 1-2 hours after being exposed to oxygen after sterilization, not during sterilization. Certainly, "within minutes" falls within "8 hours," but different things are being timed. Applicants in the first case are referring to articles of George yellowing or embrittling <u>during gamma radiation exposure</u>. Applicants in the second case are referring to devices of the present invention undergoing a visual change <u>during oxygen exposure</u>--the oxygen exposure could occur days, months, or even years after the devices were sterilized. Thus, two different times are being cited, (1) time during radiation exposure, and (2) time during oxygen exposure. Therefore, Examiner's statements referring to an "admission of within minutes" in rejecting claims 19 and 20 are in error.

Nevertheless, claims 19 and 20 are further amended to more clearly define over the cited art.

4. Regarding the claim 14 rejection based on George in view of Sleeckx, Examiner states that it would have been obvious to have used the sealable container of George with the polycarbonate plastic disclosed by Sleeckx, so as to properly shield the polycarbonate of Sleeckx from oxygen during the sterilization process to minimize yellowing. Even if this were the case, it does not lead one to the present invention. Rather, it would lead one to preventing sterilization-induced yellowing of polycarbonate. In contrast, the present invention provides a visual indication to detect oxygen exposure, even if the device were not yellowed during sterilization. Thus, the present invention is not obvious in view of the cited art.

5. Regarding the claims 15-17 rejections based on George in view of Nicolais and Ahlqvist et al., Examiner states that it would have been obvious to have used the sealable container of George with the gas-impermeable pouch of Nicolais and the laminates disclosed by Ahlqvist et al. to detect the presence of oxygen during sterilization by device yellowing during sterilization. Even if this were the case, it does not lead one to the present invention. Rather, it would lead one to detecting oxygen during sterilization only; oxygen contamination which occurred later during storage or handling would not produce the yellowing according to the teachings of the cited art. In contrast, the present invention provides a visual indication to detect oxygen exposure, even if the device were not yellowed during sterilization. Thus, the present invention is not obvious in view of the cited art.

6. Regarding the claims 9 and 18 rejections based on Ahlqvist in view of Komatsu et al., Examiner states that it would have been obvious to have used the oxygen-sensitive material of Ahlqvist to produce a package with an oxygen-

sensitive material, including the oxygen-sensitive material in the form of a chip. Even if this were the case, it would not lead one to the present invention. The goal of Ahlqvist is to avoid yellowing and physical changes which can result from irradiation in the presence of oxygen; Ahlqvist does this by using an oxygen scavenger to absorb any oxygen and allowing at least 48 hours for the absorption to take place. The present invention provides a structure which utilizes an oxygen-sensitive material which is not activated initially, allowing easier handling and processing which may include steps which expose the oxygen-sensitive material to oxygen, but becomes activated by irradiation so that subsequent exposure of the oxygen-sensitive material to oxygen is easily detectable. Thus, the present invention is not obvious in view of the cited art.

Claims 9, 19, 20, 23 and 24 have been amended. No new matter has been added.

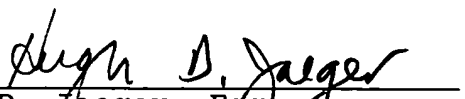
It is believed that the claims are now in condition for allowance.

If there are any further issues yet to be resolved to advance the prosecution of this patent application to issue, the Examiner is requested to telephone the undersigned counsel.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,

HUGH D. JAEGER, P.A.



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